

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

June 30, 2021

Dave Wilson Senior Regulatory Affairs Manager Bayer U.S.- Crop Science 700 Chesterfield Pkwy W Chesterfield, MO 63017

Subject: Registration Review Label Mitigation for Metalaxyl Product Name: PROCEED MD FUNGICIDE EPA Registration Number: 264-1072 Application Date: 06/28/2018 Decision Number: 576857

Dear Mr. Wilson:

The Agency, in accordance with the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, has completed reviewing all the information submitted with your application to support the Registration Review of the above referenced product in connection with Metalaxyl Interim Decision, and has concluded that your submission is acceptable. The label referred to above, submitted in connection with registration under FIFRA, as amended, is acceptable.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 12 months from the date of this letter. After 12 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently Page 2 of 2 EPA Reg. No. 264-1072 Decision No. 576857

approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

If you have any questions about this letter, please contact Srijana Shrestha by phone at 703-305-6471, or via email at shrestha.srijana@epa.gov.

Sincerely,

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Linda Arrington, Branch Chief Risk Management and Implementation Branch 4 Pesticide Re-Evaluation Division Office of Pesticide Programs

Enclosure: Stamped Label



Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 264-1072

PROTHIOCONAZOLE	GROUP	3	FUNGICIDE
TEBUCONAZOLE	GROUP	3	FUNGICIDE
METALAXYL	GROUP	4	FUNGICIDE

PROCEED[™] MD Fungicide

ABN: Raxil PRO MD

ACTIVE INGREDIENTS:

Prothioconazole: 2-[2-(1- Chlorocylocpropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]- 1,2- dihydro-3H-1,2,4-triazole-3-thion	e1.47%
Tebuconazole: (Alpha-[2-(4-chlorophenyl)ethyl]-alpha-(1,1-dimethylethyl)-1H-1,2,4-triazole-1- ethanol)	
Metalaxyl: N- (2,6-dimethylphenyl)-N-(methoxyacetyl)alanine methyl ester	
OTHER INGREDIENTS:	<u>97.65%</u>
TOTAL:	100.00%

Contains 0.128 pound prothioconazole, 0.025 pound tebuconazole and 0.052 pound metalaxyl per U.S. gallon.

EPA Reg. No. 264-1072

EPA Est.

KEEP OUT OF REACH OF CHILDREN DANGER PELIGRO

See Additional Precautionary Statements

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.

(If you do not understand the label, find someone to explain it to you in detail.)

For <u>MEDICAL</u> and <u>TRANSPORTATION</u> Emergencies <u>ONLY</u> Call 24 Hours A Day 1-800-334-7577 For <u>PRODUCT</u> <u>USE</u> Information Call 1-866-99BAYER (1-866-992-2937)

Please refer to [back panel] [booklet] for additional precautionary statements and directions for use. [Note to reviewer: Location of additional precautionary statements and directions for use will vary between those listed, depending on container type/size.]

FIRST AID

IF IN EYES:	Hold eye open and rinse slowly and gently with water for 15-20 minutes.		
	Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.		
	Call a poison control center or doctor for treatment advice.		
IF SWALLOWED:	Immediately call a poison control center or doctor for treatment advice.		
	Have person sip a glass of water if able to swallow.		
	• Do not induce vomiting unless told to do so by a poison control center or doctor.		
	Do not give anything to an unconscious person.		
IF INHALED:	Move person to fresh air.		
	• If person is not breathing, call 911 or an ambulance, and then give artificial respiration, preferably mouth-to-mouth if possible.		
	Call a poison control center or doctor for further treatment advice.		
IF ON SKIN OR CLOTHING:	Take off contaminated clothing.		
	Rinse skin immediately with plenty of water for 15-20 minutes.		
	Call a poison control center or doctor for treatment advice.		
For MEDICAL Emergencies Call 24 Hours A Day 1-800-334-7577.			
Have the product c	ontainer or label with you when calling a poison control center or doctor or going for treatment.		
NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.			

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS DANGER

Causes irreversible eye damage. Harmful if swallowed, inhaled, or absorbed through skin. Do not get in eyes or on clothing. Wear protective eyewear (goggles, face shield or safety glasses). Avoid contact with skin and breathing vapor or spray mist. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Workers involved with treating the seed (e.g. connecting and disconnecting hoses and transfer pumps, mixing, equipment calibration, etc.) and other exposed to the concentrate, and cleaners/repairers of seed treatment equipment must wear a long-sleeve shirt and long pants, shoes plus socks, protective eyewear (goggles, face shield, or safety glasses) and chemical resistant gloves such as barrier laminate, butyl rubber ≥14 mils, nitrile rubber ≥14 mills, polyvinyl chloride (PVC) ≥14 mils, and viton ≥14 mills.

Baggers and bag sewers must wear a long-sleeve shirt and long pants, and shoes plus socks.

USER SAFETY RECOMMENDATIONS

Users should wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.

Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothes.

Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to mammals, fish, aquatic invertebrates, and freshwater/estuaries/marine aquatic plants. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Runoff may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when disposing of equipment wash water or rinsate.

Cover or incorporate spilled treated seed.

Groundwater Advisory: Prothioconazole-desthio (a degradate of prothioconazole), metalaxyl and tebuconazole are known to leach through soil into ground water under certain conditions as a result of label use. Use of this product in areas where soils are permeable, particularly where the water table is shallow, may result in ground-water contamination.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

PRODUCT INFORMATION

PROCEED MD Fungicide is a combination of the systemic fungicides, prothioconazole, tebuconazole and metalaxyl which aids in the control or suppression of the following seed, seedling and soilborne diseases of wheat, barley, oats, and triticale: stinking smut, flag smut, loose smut, covered smut (common bunt), early season *Septoria* disease complex, general seed rots, *Pythium* damping-off, early season *Rhizoctonia* root rot, early season common root rot, seedborne *Fusarium* scab, barley stripe, early season *Fusarium* foot rot, early season suppression of powdery mildew (7.5 fluid ounce rate only) and rust.

In California - Registered only for use in commercial seed treating establishments. Not allowed for "on-farm" use.

USE RESTRICTIONS

- Maximum usage when applying both metalaxyl- and mefenoxam-containing products to the same crop within the same season: Do not apply more than the maximum yearly total application rate for the active ingredient as stated on the label of the product containing the lowest yearly total on that crop.
- Do not apply this product with a hopper box, planter box, slurry box, or any other at-plant methods.

APPLICATION DIRECTIONS

- Apply this product only as specified on this label. Use 5.0 7.5 fluid ounces of PROCEED MD Fungicide per 100 pounds of seed. Applications must be made using standard slurry or mist-type seed treatment equipment. In some instances, a chemical slurry dilution may enhance coverage. A 1 part PROCEED MD Fungicide with 1 part water dilution may be used.
- This product is for commercial or on-farm application. Uniform application to seed is necessary to ensure seed safety and best disease control. Only use seed that is sound and well cured prior to treatment. Consult your area agronomist regarding planting depth recommendations for the particular variety to be planted.

RESISTANCE MANAGEMENT RECOMMENDATION

For resistance management, please note that PROCEED MD contains two Group 3 (demethylation inhibitors) and a Group 4 (phenylamides) fungicide. Any fungal population may contain individuals naturally resistant to PROCEED MD and other Group 3 or Group 4 fungicides. A gradual or total loss of pest control may occur over time if these fungicides are used repeatedly in the same fields. Appropriate resistance-management strategies should be followed.

To delay fungicide resistance, take one or more of the following steps:

- Rotate the use of PROCEED MD or other Group 3 and 4 fungicides within a growing season sequence with different groups that control the same pathogens.
- Use tank mixtures with fungicide from a different group that are equally effective on the target pest when such use is permitted. Use at least the minimum application rate as labeled by the manufacturer.
- Adopt an integrated disease management program for fungicide use that includes scouting, uses historical information related to pesticide use, and crop rotation, and which considers host plant resistance, impact of environmental conditions on disease development, disease thresholds, as well as cultural, biological and other chemical control practices.
- Where possible, make use of predictive disease models to effectively time fungicide applications. Note that using predictive models alone is not sufficient to manage resistance.
- Monitor treated fungal populations for resistance development.
- Contact your local extension specialist or certified crop advisor for any additional pesticide resistance-management and/or IPM recommendations for specific crops and pathogens.
- For further information or to report suspected resistance contact Bayer CropScience LP at 1-866-99BAYER (1-866-992-2937). You can also contact your pesticide distributor or university extension specialist to report resistance.

SEED BAG TAG

The Federal Seed Act requires that the container of seed treated with PROCEED MD Fungicide must be labeled with the following statements:

This seed has been treated with PROCEED MD Fungicide, which contains 1.47% of Prothioconazole, 0.29% of Tebuconazole, and 0.59% of Metalaxyl.

- Do not use treated seed for food, feed, or oil purposes. Excess treated seed may be used for ethanol production only if (1) byproducts are not used for livestock feed and (2) no measurable residues of pesticide remain in ethanol by-products that are used in agronomic practice.
- Barley, wheat, oats, and triticale green forage may be grazed or harvested for hay 31 days after seeding.
- Store treated seeds away from food and feedstuffs.
- Do not allow children, pets, or livestock to have access to treated seed.
- Wear long-sleeved shirt, long pants and chemical-resistant gloves when handling treated seed.
- Treated seeds exposed on soil surface may be hazardous to wildlife. Cover or collect treated seeds spilled during loading.
- Dispose of all excess treated seed. Leftover treated seed may be buried away from water sources in accordance with local requirements.
- Do not contaminate water bodies when disposing of planting equipment wash waters.
- Treated seed must be adequately covered with soil at planting.
- Dispose of seed packaging or containers in accordance with local requirements. Do not use empty seed bags for any other purpose.
- To reduce seed dust which can drift onto blooming crops or weeds, ensure that planting equipment is functioning properly in accordance with manufacturer's recommendations. Surplus seed or empty seed containers should be stored or disposed according to local federal regulations.
- Treated at manufacturer's recommended rate

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage, disposal, or by cleaning of equipment. **PESTICIDE STORAGE**

Keep out of reach of children and animals. Store in original containers only. Store in a cool, dry place and avoid excess heat

PESTICIDE DISPOSAL

Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance

CONTAINER HANDLING

[Dilutable Seed Treatment Products in Non-Refillable Plastic Containers]

Rigid Non-refillable containers that are too large to shake (i.e., with capacities greater than 5 gallons or 50 lbs) Non-refillable container. Do not reuse or refill this container. After emptying product from container, either return container to Bayer CropScience per instructions from Bayer CropScience Customer Service Center (1-800-527-4781), or rinse and either recycle or dispose of the container as follows:

Bottom Discharge IBC (e.g. - Schuetz Caged IBC or Snyder Square Stackable)

Pressure rinsing the container before final disposal is the responsibility of the person disposing of the container. To pressure rinse the container before final disposal, empty the remaining contents from the IBC into application equipment or mix tank. Raise the bottom of the IBC by 1.5 inches on the side which is opposite of the bottom discharge valve to promote more complete product removal. Completely remove the top lid of the IBC. Use water pressurized to at least 40 PSI to rinse all interior portions. Continuously pump or drain rinsate into application equipment or rinsate collection system while pressure rinsing. Continue pressure rinsing for 2 minutes or until rinsate becomes clear. Replace the lid and close bottom valve.

Top Discharge IBC, Drums, Kegs (e.g. – Snyder 120 Next Gen, Bonar B120, Drums, and Kegs)

Triple rinsing the container before final disposal is the responsibility of the person disposing of the container. To triple rinse the container before final disposal, empty the remaining contents from this container into application equipment or mix tank. Fill the container at least 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Rinse all interior surfaces. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this procedure two more times.

Once container is rinsed, offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration.

[Dilutable Seed Treatment Products in Non-Refillable Metal Containers]

Nonrefillable container. Do not reuse or refill this container. After emptying product from container, either return container to Bayer CropScience per instructions from Bayer CropScience Customer Service Center (1-800-527-4781), or rinse and either recycle or dispose of the container as follows:

Liquid dilutables in containers small enough to shake (5 gallons or less)

Triple Rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

Solid dilutables in containers small enough to shake (5 gallons or 50 pounds or less)

Triple Rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

Any dilutable pesticides in containers too large to shake (larger than 5 gallons or 50 pounds)

Triple Rinse as follows: Empty remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times.

Once container is rinsed, offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration.

[Non-Dilutable Seed-Treatment Products in Non-Refillable Containers]

Seed-Treatment Products in Non-Refillable Fiber Drums with Liners

Non-refillable container. Do not reuse or refill this container. Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment, then offer for recycling if available or dispose of in a sanitary landfill or by incineration. If drum is contaminated and cannot be reused, dispose of it in the manner required for its liner.

Seed-Treatment Products in Non-rigid, Non-Refillable Containers

Nonrefillable container. Do not reuse or refill this container. Completely empty container into application equipment. Then offer for recycling if available or dispose of in a sanitary landfill or by other procedures approved by state and local authorities.

[Seed Treatment Products in Refillable Containers]

Refillable container. Refill this container with pesticide only. Do not reuse this container for any other purpose. After emptying product from container, either return container to Bayer CropScience per instructions from Bayer CropScience Customer Service Center (1-800-527-4781) or rinse and either recycle or dispose of the container as follows:

Bottom Discharge IBC (e.g. - Schuetz Caged IBC or Snyder Square Stackable)

Pressure rinsing the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To pressure rinse the container before final disposal, empty the remaining contents from the IBC into application equipment or mix tank. Raise the bottom of the IBC by 1.5 inches on the side which is opposite of the bottom discharge valve to promote more complete product removal. Completely remove the top lid of the IBC. Use water pressurized to at least 40 PSI to rinse all interior portions. Continuously pump or drain rinsate into application equipment or rinsate collection system while pressure rinsing. Continue pressure rinsing for 2 minutes or until rinsate becomes clear. Replace the lid and close bottom valve.

Top Discharge IBC, Drums, Kegs (e.g. - Snyder 120 Next Gen, Bonar B120, Drums, and Kegs)

Triple rinsing the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To triple rinse the containers before final disposal, empty the remaining contents from this container into application equipment or mix tank. Fill the container at least 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Rinse all interior surfaces. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this procedure two more times.

Once container is rinsed, offer for recycling if available or puncture and dispose of in a sanitary landfill or by incineration.

End users are authorized to remove tamper evident cables as required to remove the product from the container unless the container is equipped with one way valves and refilling or returning is planned. If this is the case, end users are not authorized to remove tamper evident cables, one way valves or clean container.

IMPORTANT: READ BEFORE USE

Read the entire Directions for Use, Conditions, Disclaimer of Warranties and Limitations of Liability before using this product. If terms are not acceptable, return the unopened product container at once.

By using this product, user or buyer accepts the following Conditions, disclaimer of Warranties and Limitations of Liability.

Treatment of highly mechanically damaged seed, or seed of known low vigor and poor quality, may result in reduced germination and/or reduction of seed and seedling vigor. Treat and conduct germination tests on a small portion of seed before committing the total seed lot to a selected chemical treatment. Due to seed quality conditions beyond the control of Bayer CropScience, no claims are made to guarantee germination of carry-over seed.

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Bayer CropScience. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, all such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE MAKES NO WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. No agent of Bayer CropScience is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT.

LIMITATIONS OF LIABILITY: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, SHALL NOT EXCEED THE PURCHASE PRICE PAID, OR AT BAYER CROPSCIENCE'S ELECTION, THE REPLACEMENT OF PRODUCT.

NET CONTENTS:

PROCEED is a trademark of Bayer CropScience LP

PRODUCED FOR



Bayer CropScience LP 800 N. Lindbergh Blvd. St. Louis, MO 63167 1-866-99BAYER (1-866-992-2937)

PROCEED MD Fungicide (PENDING) 06/26/2018, 05/07/2021, 06/21/2021